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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,285	02/01/2002	Greg Fahy	074066-0115	3778
30542	7590	11/04/2004	EXAMINER	
FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,285

Applicant(s)

FAHY ET AL.

Examiner

Sandra Saucier

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 0749.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 36-57 and 59-66 is/are pending in the application.
4a) Of the above claim(s) 37-49, 51-57 and 59-66 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 36 and 50 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6, 36-57, 59-66 are pending. Claims 1-6, 36 and 50 are considered on the merits. Claims 37-49, 51-57, 59-66 are withdrawn from consideration as being drawn to a non-elected invention.

Please use the term, "withdrawn" for the claims which have been withdrawn. A notice of non-compliance will be sent out if the claims are not properly identified in the next response.

Election/Restrictions

Newly submitted claims directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- I. Claims 1-6, 36 and 50, drawn to a composition comprising polyglycerol, lactose having a total concentration of 20-250mOsmolal and glutathione.
- II. Claims 37-39, drawn to a second composition comprising polyglycerol, lactose in the claimed concentration and chondroitin sulfate
- III. Claims 40-42, drawn to a third composition comprising polyglycerol, lactose in the claimed concentration and chlorpromazine,
- IV. Claims 43, 51, drawn to a fourth composition comprising polyglycerol, lactose in the claimed concentration and citrate
- V. Claim 44, drawn to a fifth composition comprising polyglycerol, lactose in the claimed concentration and calcium.
- VI. Claim 45, drawn to a fifth composition comprising polyglycerol, lactose in the claimed concentration and magnesium.

- VII. Claim 46, drawn to a sixth composition comprising polyglycerol, lactose in the claimed concentration and adenine.
- VIII. Claim 47, drawn to a seventh composition comprising polyglycerol, lactose in the claimed concentration and glucose.
- IX. Claim 48, drawn to a eighth composition comprising polyglycerol, lactose in the claimed concentration and acetate.
- X. Claim 49, drawn to a ninth composition comprising polyglycerol, lactose in the claimed concentration and phosphate buffer.

The compositions are distinct because they have distinct components and have been newly presented because of applicant's amendments.

Please note that a composition A may not be restricted from compositions A+B, or from A+B+C, or from A+B+C+D as these form a tree of further limitations. However, compositions A+B and A+C and A+D, etc. are distinct compositions and may be properly restricted as they have been above.

Since applicant has received an action on the merits for the originally presented invention, Group I, polyglycerol, lactose in the claimed concentration and glutathione, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-49 and 51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Please look at the restriction requirement mailed 7/2/03, where this restriction was originally delineated. Prosecution should proceed in a logical, linear fashion. Amending claims to incorporated issues which have already been resolved adds to confusion and needless prolongation of prosecution.

See also applicant's response to the restriction requirement where the examiner's explanation of the restriction requirement was acknowledged and the principle appears to be understood.

Upon indication of allowability, other claims dependent on the allowed claim may be introduced as long as no issues of new matter or enablement or indefiniteness are raised. Applicants did not incorporate the limitations indicated as allowable by the examiner, but instead added new matter to the claims and then attempted to incorporate restricted matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 36 and 50 remain provisionally rejected under the judicially created doctrine of double patenting over claims 6, 18, 21 of copending

Application No. 09/916396. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a solution comprising lactose and polyglycerol.

Claim Rejections – 35 USC § 112

Claims 1–6, 36 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite that the solution which comprises lactose and polyglycerol has a total osmotic concentration of 20–250mOsM. The specification states on page 3 that the sum of lactose + polyglycerol osmolality (in the solution) is preferably from 20–250mOsm. This is different from a solution with a total osmolality of 20–250mOsm, where the solution is open to further additions. While support might be found for a solution *consisting of* polyglycerol and lactose with a total osmotic concentration in the range of 20–250 mOsm, no support exists for the instant claims.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection over the claims. However, removal of new matter will result in the reinstatement of the art rejection.

Claim Rejections – 35 USC § 103

Claims 1–6, 36, 50 are not longer rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,19,137 [B] in view of US 6,616,858 [A] or Klebe *et al.* [U] because of the insertion of new matter.

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Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

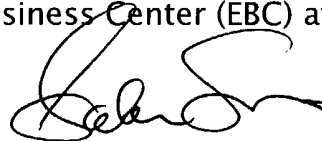
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', is positioned above the printed name.

Sandra Saucier
Primary Examiner
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